TECHNOPATH

**510(k) Summary**
**Multichem WBT Control**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: **K132174**

## 1.0 Submitter

Paula McCarthy
Head of Quality and Regulatory Affairs
Technopath
Fort Henry Business Park
Ballina, Co. Tipperary
Ireland
Telephone: + 353 61 335844
Fax: + 353 61 203034
Email: paula.mccarthy@techno-path.com

SEP 20 2013

## 2.0 Date Sumbitted

August 16, 2013

## 3.0 Device Identification

| | |
|---|---|
| Proprietary Names: | Multichem WBT |
| Common Name: | Drug mixture and clinical toxicology control materials |
| Classification: | Class 1, Reserved |
| Product Code: | DIF |
| Regulation Number: | 21 CFR 862.3280 |

## 4.0 Legally Marketed Predicate Device

| Candidate(s) | Predicate | Manufacturer | Document Number |
|---|---|---|---|
| Multichem WBT | Lyphocheck® Whole Blood Immunosuppressant Control | Bio-Rad Laboratories | K072721 |

The Multichem WBT control is substantially equivalent to the Bio-Rad product listed above, currently in commercial distribution.

T E C H N O P A T H

## 5.0 Device Description

Technopath has developed whole blood control materials prepared from human whole blood, to which whole blood purified biochemical material (extracts of human origin), chemicals, drugs, preservatives and stabilizers have been added. Three levels of control are available to allow performance monitoring within the analytical range.

Each donor unit used in the preparation of the control material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV, and nonreactive for HBsAg; However, because no test method can offer complete assurance that HIV, hepatitis B virus and hepatitis C virus or other infectious agents are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. It is recommended that this material be handled in accordance with the OSHA Standard on Blood borne Pathogens.

## 6.0 Intended Use

The Multichem WBT control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. The Multichem WBT control consists of 3 different levels of control solutions prepared from human whole blood.

IRL Tel: +353 (0) 61 335844
IRL Fax: +353 (0) 61 203034
UK Tel: +44 (0) 28 30833808
UK Fax: +44 (0) 28 30833650

TECHNOPATH
Fort Henry Business Park,
Ballina, Co Tipperary, Ireland.
E-mail: info@techno-path.com

TECHNOPATH Manufacturing.
Registered in Ireland no. 419288
Registered office as above
www.techno-path.com

## 7.0 Comparison to the Predicate

Multichem WBT control claims to be substantially equivalent to Lyphochek® Whole Blood Immunosuppressant Controls. The controls have same/similar design and modes of operation. The key features are summarized in the following table.

| Characteristics | Predicate Device: Lyphochek® Whole Blood Immunosuppressant Controls | Proposed Device: Multichem WBT Controls |
|---|---|---|
| **Similarities** | | |
| Intended Use: | Lyphochek® Whole Blood Immunosuppressant - is intended for use as assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. | Multichem WBT is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. |
| Analytes | Cyclosporine<br>Sirolimus<br>Tacrolimus | Cyclosporine<br>Sirolimus<br>Tacrolimus |
| **Differences** | | |
| Form: | Lyophilized | Liquid, Frozen |
| Matrix: | EDTA Whole Blood | Processed Human Whole Blood Hemolysate |
| Storage (Closed/Shelf-Life) | 2 to 8°C until expiration date | 30 months at -20° to -80°C |
| Open Vial | 14 days at 2 to 8°C | Tacrolimus and Cyclosporine 10 days at 2 to 8°C<br>Sirolimus 7 days at 2 to 8°C |

## 8.0 Performance Characteristics

### 8.1 Traceability Summary

The analytes contained within the Multichem WBT control Level, 1, 2 and 3 were obtained from commercially available sources or are endogenous to the base

matrix. Technopath does not claim traceability to higher order reference materials or methods.

## 8.2 Value Assignment Summary

Value assignment testing was internally performed and utilized internal procedures and protocols to determine typical values that would be seen for the product across Abbott ARCHITECT i2000® chemistry system with the associated reagent test systems. For the Multichem WBT control, 2 reagent lots and 2 calibrator lots were used to incorporate reagent and calibrator variation. 2 replicates from 16 runs were performed to give a total of 32 data points. Distinct runs, with minimum gaps of 2 hours were performed and a minimum of 8 calibration events were performed to incorporate variation from calibration and environmental sources. Value assignment ranges were established at the pre-determined criteria of 30% around the grand mean to ensure that 3SD's either side of the mean were within the established range. Values for the lots tested all fell within the established ranges.

## 8.3 Stability Testing Summary

Stability studies have been performed to determine the open vial stability and shelf-life for this control. For open vial stability, Technopath utilized internal procedures and Isochronous - Staggered Start [Backwards / Back-ended] method from CLSI EP25A entitled "Evaluation of Stability of *In Vitro* Diagnostic Reagents." To minimize variation, where possible, one lot of reagent, calibrator and reference/control was used for the entire study, per analyte. Testing was performed over multiple days on 1 Abbott ARCHITECT i2000® instrument with the associated reagent test systems. All Multichem WBT analytes for open vial testing used freshly thawed vial samples that were tested in replicates of 3 at each time point. Multiple time points were tested and the point of failure was determined by the maximum allowable drift (degradation), which was determined to be 10%.

Product claims are as follows:

Open Vial Stability:

- Tacrolimus and Cyclosporine 10 days at 2 to 8°C
- Sirolimus 7 days at 2 to 8°C

IRL Tel: +353 (0) 61 335844
IRL Fax: +353 (0) 61 203034
UK Tel: +44 (0) 28 30833808
UK Fax: +44 (0) 28 30833650

TECHNOPATH
Fort Henry Business Park,
Ballina, Co Tipperary, Ireland
E-mail: info@techno-path.com

TECHNOPATH Manufacturing.
Registered in Ireland no. 419288
Registered office as above
www.techno-path.com

T E C H N O P A T H

A combination of accelerated and real-time testing was carried out utilizing CLSI EP25A in order to support a shelf-life storage claim of -20° to -80°C for 30 months. The accelerated testing utilized three lots of controls and the preliminary real-time testing utilized three lots of controls. All data was generated using the Abbott ARCHITECT i2000® instrument with the associated reagent test systems. For the Multichem WBT control, the Drift Limit was determined to be 10%. These results concluded that the Multichem WBT control product is predicted to be stable for in excess of 30 months when stored at -20°C to -80°C. The real-time testing is on-going.

Product claims are as follows:

Storage (Closed/Shelf-Life):

- 30 months at -20° to -80°C

## 9.0 Conclusion:

The conclusions drawn from the nonclinical tests (discussed above) demonstrate that the Multichem WBT control is as safe, as effective, and performs as well as the predicate device. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 20, 2013

Techno-path Manufacturing Ltd.
C/O Stephanie Garth, Consultant
Global Compliance Plus
325 Big Elm St.
HIGHLAND VILLAGE TX 75077

Re: K132174
Trade/Device Name: Multichem WBT
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical toxicology control material
Regulatory Class: Class I, reserved
Product Code: DIF
Dated: August 16, 2013
Received: August 19, 2013

Dear Ms. Garth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use Form

510(k) Number (if known): k132174

Device Name: Multichem WBT

Indications for Use:

The Multichem WBT control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. The Multichem WBT control consists of 3 different levels of control solutions prepared from human whole blood.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-lyles -S
2013.09.18 08:51:50 -04'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k132174